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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/596,103 | 05/30/2006 | Peter Petzelbauer | 1848-7 PCT/US | 2050 |

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| EXAMINER | |
|---|---|
| HA, JULIE | |

| ART UNIT | PAPER NUMBER |
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| 1654 | |

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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

| **Advisory Action Before the Filing of an Appeal Brief** | **Application No.** 10/596,103 | **Applicant(s)** PETZELBAUER ET AL. | |
|---|---|---|---|
| | **Examiner** JULIE HA | **Art Unit** 1654 | |

***--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --***

THE REPLY FILED 10 November 2010 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:
   a) ☒ The period for reply expires *3* months from the mailing date of the final rejection.
   b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

   Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☐ The Notice of Appeal was filed on _____. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☐ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
   (a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);
   (b) ☐ They raise the issue of new matter (see NOTE below);
   (c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
   (d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

   NOTE: _____. (See 37 CFR 1.116 and 41.33(a)).
4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
5. ☐ Applicant's reply has overcome the following rejection(s): _____.
6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
7. ☒ For purposes of appeal, the proposed amendment(s): a) ☐ will not be entered, or b) ☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.
   The status of the claim(s) is (or will be) as follows:
   Claim(s) allowed: _____.
   Claim(s) objected to: _____.
   Claim(s) rejected: *17-64*.
   Claim(s) withdrawn from consideration: _____.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because: Please see continuation of 11 below.
12. ☐ Note the attached Information *Disclosure Statement*(s). (PTO/SB/08) Paper No(s). _____
13. ☐ Other: _____.

/Julie Ha/
Primary Examiner, Art Unit 1654

Continuation of 11:

For the record, the Examiner at page 9 did not misquote Applicant's statement. At top of page 9 of office action mailed on August 17, 2010, the Examiner recited:

"Applicants argue that method of treating inflammation are distinct from method of treating shock…the disclosure of method of treating shock or preventing inflammation in reference WO 02/48180 was found to not be of particular relevance to the determination of novelty and inventive step of method of treating shock in the presently claimed invention."

It is unclear where in the statement above states "…the disclosure of method of shock (sic) or preventing inflammation…", as Applicant indicates.

Claims 17-28, 30-32, 36-38, 42-44, 48-50, 54-56 and 60-62 remain rejected under 35 U.S.C. 102(e) as being anticipated by Petzelbauer P (US 2004/0192596 A1), as set forth in the previous office action.

Claims 17-28, 30-32, 36-38, 42-44, 48-50, 54-56 and 60-62 remain rejected under 35 U.S.C. 102(e) as being anticipated by Petzelbauer P 2007/0037749 A1), as set forth in the previous office action.

Claims 17-28, 30-32, 36-38, 42-44, 48-50, 54-56 and 60-62 remain rejected under 35 U.S.C. 102(b) as being anticipated by Petzelbauer (WO 02/48180 A2), as set forth in the previous office action.

Applicant argues that "Although US 2004/0192596, US 2007/0037749, WO 02/48180 and the instant application include the step of administering a peptide having the sequence of SEQ ID NO: 8 of the instant application, the therapeutic indication for which the peptide is administered differs between the cited art and the instant application. Likewise, the patient population receiving the peptide for such indication is not necessarily the same patient population. Nowhere do any of US 2004/0192596, US 2007/0037749, WO 02/48180 disclose or suggest method for treating shock using such peptides…a skilled artisan would not have a reasonable expectation of success in treatint shock based on the disclosure of US 2004/0192596, US 2007/0037749 or WO 02/48180."

Applicant's argument have been fully considered but have not been found persuasive. The claims are drawn to a method of treating shock comprising administering to a subject a therapeutically effective amount of a peptide of formula II. The claims do not define a patient population, thus anybody being administered the peptide of formula II would inherently be treated for shock. The references teach all of the active method steps of instant application. Furthermore, as described in the response to Applicant's arguments (pp. 4-5, 6-7 and 9) the US 2004/0192596 teaches the method of preveting inflammation in a subject comprising administering to the subject an effective amount of peptide having the formula II, wherein the inflammation is due to a condition selected from the group consisitng of an infection, an autoimmune condition, a rheumatic disorder, or a disorder of the immune system (claims 14 and 21 of '596). Since the cause that leads to inflammation and shock is the same, the method of treating inflammation would necessarily treat shock. US 2007/0037749 also teaches that the inflammation is due to a condition selected from the group consisting of an infection, an autoimmune condition, a rheumatic disorder, or a disorder of the immune system (claim 3 of '749). Since the cause that leads to inflammation and shock is the same, and the reference claims a method of treating inflammation in a subject (claims 1-4), a method of inhibiting inflammation of a transplanted tissue in a subject (claims 5-6), the method of treating inflammation and inhibiting inflammation in a transplanted tissue would necessarily treat shock. WO 02/48180 also teaches a method of treating inflammation due to a condition selected from the group consisting of an infection, an autoimmune condition, a rheumatic disorder, or a disorder of the immune system (claims 7-17 of '180). Since the cause that leads to inflammation and shock is the same, the method of treating inflammation would necessarily terat shock, and vice versa. Therefore, the rejections are maintained.

Claims 17-28, 30-32, 36-38, 42-44, 48-50, 54-56 and 60-62 remain rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-4 of US Patent No. 7,271,144, as set forth in the previous office action.

Claims 17-28, 30-32, 36-38, 42-44, 48-50, 54-56 and 60-62 remain provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-4 of copending application No. 11/899,611, as set forth in the previous office action.

Claims 17-28, 30-32, 36-38, 42-44, 48-50, 54-56 and 60-62 remain rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-3 US patent No. 7,494,973, as set forh in the previous office action.

Claims 17-28, 30-32, 36-38, 42-44, 48-50, 54-56 and 60-62 remain provisionally rejected on the ground of nonstatutory obviousness-double patenting as being unpatentable over claims 6-7 of copending application no. 12/121,533, as set forth in the previous office action.

Claims 17-28, 30-32, 36-38, 42-44, 48-50, 54-56 and 60-62 remain provisionally rejected on the ground of nonstatutory obviousness-double patenting as being unpatentable over claims 6-7 of copending application no. 12/121,544, as set forth in the previous office action.

Claim 17-28, 30-32, 36-38, 42-44, 48-50, 54-56 and 60-62 remain provisionally rejected on the ground of nonstatutory obviousness-double patenting as being unpatentable over claims 1-2 and 4-5 of copending application no. 12/158,670, as set forth in the previous office action.

Applicant argues that "As discussed in the 35 USC 102 rejections, methods of treating shock disclsoed in the instant application are neither anticipated nor rendered obvious by methods of treating inflammation disclsoed in US 2004/0192596 and US 2007/0037749...the methods of treating shock disclsoed in the instant application are not rendered obvious by methods of treating inflammation disclsoed in US Patent No. 7,271,144, US Patent No. 7,494,973 and US Application 11/899,611."

Applicant argues that "the instant application was filed on June 24, 2005 claims priority to Austrarian application A1087/2004 filed on June 25, 2004 and Austrian Application A40/2005 filed on January 13, 2005. Thus the subject application preces US Application Nos.

12/121,533, filed May 15, 2008, 12/121,544, filed May 15, 2008 and 12/158,670, filed September 5, 2008 which claims priority to Austrian application A2067/2005, filed December 23, 2005. Upon issuance, the instant application would presumably exppire prior to the expiration of any patent issuing based on US application Nos. 12/121,533, 12/121,544 or 12/158,670…Upon indication of allowable subjet matter, Applicants will consider the need to file one or more terminal disclaimers to overcome these obviouness-type double patenting rejections."

Applicant's arguments have been fully considered but have not been found persuasive. As indicated above, the claims are drawn to a method of treating shock comprising administering to a subject a therapeutically effective amount of a peptide of formula II. The claims do not define a patient population, thus anybody being administered the peptide of formula II would inherently be treated for shock. The references teach all of the active method steps of instant application. In regards to later-filed applications, the MPEP states that "If provisional" ODP rejections in two applications are the only rejections remaining in those applications, the examiner should withdraw the ODP rejetion in the earlier filed application thereby permitting that application to issue without need of a terminal disclaimer" (see MPEP 804). Since there are other rejections remaining in the application, the ODP rejections are maintained.

Claims 17-32, 35-38, 41-44, 47-50, 53-56 and 59-62 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Petzelbauer (WO 02/48180 A2) in view of Bevec et al (US 2004/0122058), as set for the in the previous office action.

Claims 17-28, 30-33, 36-39, 42-45, 48-51, 54-57 and 60-63 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Petzelbauer (WO 02/48180 A2) in view of Thurkauf et al (WO 02/49993), as set for the in the previous office action.

Claims 17-28, 30-34, 36-40, 42-46, 48-52, 54-58 and 60-64 35 U.S.C. 103(a) as being unpatentable over Petzelbauer (WO 02/48180 A2) in view of Yat (WO 94/07815), as set for the in the previous office action.

Applicant argues that "as discussed in the 35 USC 102 rejection above, methods for treating shock differ from methods for preventing or treating inflammation. Nowhere does WO 02/48180 disclose or suggest methods for treating shock...skilled artisan would not have a reasonable expectation of success in treating shock based on the disclosure of WO 02/48180 as, independent of cause, the manifestation of shock is different from inflammation and the patient population treated for each therapeutic indication is not necessarily the same.

Applicant's arguments have been fully considered but have not been found persuasive. As discussed above, the claims are drawn to a method of treating shock comprising administering to a subject a therapeutically effective amount of a peptide of formula II. The claims do not define a patient population, thus anybody being administered the peptide of formula II would inherently be treated for shock. The references teach all of the active method steps of instant application. Once the same compound is administered to a patient population, this would necessarily treat shock, since patient population is not defined. As set forth in the previous office action, the combined prior arts are prima facie obvious over the instant claims as indicated in the rejections.